(3) In selecting the members of the committee, the organization involved is to apply the principles relating to conflicts of interest that FDA uses in establishing a public advisory committee. Those principles are set out or cross-referenced in this part and in part 19. Upon request, FDA will assist or provide guidance to any organization in meeting this requirement.

Subpart B—Meeting Procedures

§ 14.20 Notice of hearing before an advisory committee.

(a) Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the FEDERAL REGISTER of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the FEDERAL REGISTER on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the FEDERAL REGISTER.

(b) The FEDERAL REGISTER notice will include—

(1) The name of the committee;

(2) The date, time, and place of the meeting;

(3) The general function of the committee;

(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting;

(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions;

(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting;

(7) The time set aside for oral statements and other public participation;

(8) The name, address, and telephone number of the advisory committee executive secretary and any other agency employee designated as responsible for the administrative support for the advisory committee;

(9) A statement that written submissions may be made to the advisory committee through the executive secretary at any time, unless a cutoff date has been established under § 14.35(d)(2);

(10) When a notice is published in the FEDERAL REGISTER less than 15 days before a meeting, an explanation for the lateness of the notice; and

(c) If a public hearing before an advisory committee is used in lieu of a formal evidentiary public hearing under § 14.1(a)(3), an initial notice of hearing is to be published separately in the FEDERAL REGISTER containing all the information described in § 12.32(e). This procedure may be used for any other hearing before an advisory committee when the Commissioner concludes, as a matter of discretion, that it would be informative to the public.

(d) A list of advisory committee meetings will be distributed to the press by the Associate Commissioner for Public Affairs.

(e) All advisory committee meetings are to be included on the public calendar described in § 10.100(a).

[44 FR 22351, Apr. 13, 1979, as amended at 47 FR 26375, June 1, 1982; 54 FR 9035, Mar. 3, 1989]

§ 14.22 Meetings of an advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or alternate. No meeting may be held in the absence of the designated Federal employee.

(1) If any matter is added to the agenda after its publication in the FEDERAL REGISTER under § 14.20(b)(4), an attempt is to be made to inform persons known to be interested in the matter, and the change is to be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting is to be conducted in accordance with the approved final agenda insofar as practical.

(b) Advisory committee meetings will be held at places that are reasonably accessible to the public. All advisory committee meetings will be held

in Washington, DC, or Rockville, MD, or the immediate vicinity, unless the Commissioner receives and approves a written request from the advisory committee for a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the Government will be reduced.

(2) A substantial number of the committee members will be at the location at no expense to FDA for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location more readily accessible to committee members.

(4) There is a need for increased participation available at that location.

(5) The committee wishes to review work or facilities in a specific location.

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Board of Tea Experts and the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in Brooklyn, NY, and in the Little Rock, AR, vicinity, respectively.

(c) Advisory committee members may, with the approval of FDA, conduct onsite visits relevant to their work.

(d) Unless the committee charter provides otherwise, a quorum for an advisory committee is a majority of the current voting members of the committee, except as provided in §14.125(c) for TEPRSSC. Any matter before the advisory committee is to be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the committee. Any current voting member of the committee may file a separate report with additional or minority views.

(e) If space is available, any interested person may attend any portion of any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings are to be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room is to be reasonable, considering such factors as the size of the committee, the number of persons expected to attend a meeting, and the resources and facilities available.

(g) The Commissioner may authorize a meeting to be held by conference telephone call. For these meetings, a speaker phone will be provided in a conference room located in Washington, DC, or Rockville, MD, or the immediate vicinity, to permit public participation in open portions of the meetings, as provided in §§14.25 and 14.29. These meetings generally will be brief, and authorized—

(1) For the purpose of taking final votes or otherwise confirming actions taken by the committee at other meetings; or

(2) Where time does not permit a meeting to be held at a central location.

(h) Any portion of a meeting will be closed by the committee chairman only when matters are to be discussed which the Commissioner has determined may be considered in closed session under §14.27(b). If a portion of the meeting is closed, the closed portion will be held after the conclusion of the open portion whenever practicable.

(i) Any committee member may take notes during meetings and report and discuss committee deliberations after a meeting is completed and before official minutes or a report are available, within the rules and regulations adopted by FDA and by the advisory committee with the concurrence of FDA, including all of the following:

(1) There may be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There may be no reporting or discussion of any particular matter if the committee or FDA specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision that requires preparation or implementation.

(3) There may be no reporting or discussion of information prohibited from public disclosure under §14.75.

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee. It is the responsibility of each committee member to make certain that the official minutes and reports are complete and accurate and

fully reflect what happened at any meeting the committee member attended.

[44 FR 22351, Apr. 13, 1979; 48 FR 40887, Sept. 12, 1983, as amended at 54 FR 9035, Mar. 3, 1989]

§14.25 Portions of advisory committee meetings.

An advisory committee meeting has the following portions:

(a) *The open public hearing.* Every committee meeting includes an open portion, which constitutes a public hearing during which interested persons may present relevant information or views orally or in writing. The hearing is conducted in accordance with §14.29.

(b) *The open committee discussion.* A committee discusses any matter pending before it in an open portion of its meeting unless the meeting has been closed for that matter under §14.27. To the maximum extent feasible, consistent with the policy expressed in §14.27, a committee conducts its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the committee chairman.

(c) *The closed presentation of data.* Information prohibited from public disclosure under part 20 and the regulations referenced therein is presented to the committee in a closed portion of its meeting. However, if information is in the form of a summary that is not prohibited from public disclosure, the presentation is to be made in an open portion of a meeting.

(d) *The closed committee deliberations.* Deliberations about matters before an advisory committee may be held in a closed portion of a meeting only upon an appropriate determination by the Commissioner under §14.27.

§14.27 Determination to close portions of advisory committee meetings.

(a) No committee meeting may be entirely closed. A portion of a meeting may be closed only in accordance with a written determination by the Commissioner under this section.

(b) The executive secretary or other designated agency employee shall prepare the initial request for a determination to close a portion of a meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, will determine whether to close a portion of a meeting. The reasons for closing a portion of a meeting will be announced in the FEDERAL REGISTER notice of the meeting under §14.20 in accordance with the following rules:

(1) Any determination to close a portion of a meeting restricts the closing to the shortest possible time consistent with the policy in this section.

(2) A portion of a meeting may be closed only if the Commissioner determines that the closing is permitted under 5 U.S.C. 552b(c), and that the closing is necessary.

(3) Portions of meetings may ordinarily be closed if they concern the review, discussion, and evaluation of drafts or regulations, guidelines or similar preexisting internal agency documents, but only if their premature disclosure would significantly impede proposed agency action; review of trade secrets and confidential commercial or financial information; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(4) Portions of meetings ordinarily may not be closed if they concern review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs and devices; review of information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other information not exempt from public disclosure under 5 U.S.C. 552b(c); the formulation of advice and recommendations to FDA on matters that do not independently justify closing.

(5) No portion of a meeting devoted to matters other than those designated in paragraph (b) (1) through (3) of this section may be closed.